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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,681	09/23/2005	Gerald McMorow	DXUC-1-1043	5818
25315 7590 11/06/2007 BLACK LOWE & GRAHAM, PLLC 701 FIFTH AVENUE SUITE 4800 SEATTLE, WA 98104			EXAMINER LAMPRECHT, JOEL	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 11/06/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/523,681

Applicant(s)

MCMORROW ET AL.

Examiner

Joel M. Lamprecht

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 8/20/07 have been fully considered but they are not persuasive. The Examiner fundamentally disagrees with the premise of the arguments leveled against the rejection of record. In particular regarding the argument that Ganguly et al. fails to disclose the transmittal of a fundamental ultrasound frequency of at least one ultrasonic power to the body, and receiving echoes having a fundamental frequency and at least one harmonic frequency the Examiner would like to clarify the definition of fundamental frequency, that being "the lowest frequency of some harmonic series". The fundamental frequency can also be interpreted as the "first harmonic" frequency. The essence of an acoustic signal or transmit/receive signal from an ultrasound system is that the system operates at a *frequency*. Referring to Ganguly et al Col 3 Line 55-Col 4 Line 25 it is mentioned that ultrasound beams are transmitted to the body in the bladder region and then received once reflected from the body (at various delay times based on how deep the signal reached). The A-line data, which is thereby acquired, is based on the frequency of the transmitted signal(s) and received signal(s). Inherent properties of ultrasound waves or any waveform for that matter would fall under unpatentable material under USC 101 as they are simply a property of any waveform. The modulation or modification of such waves would be statutory; however every wave system has a fundamental frequency, which is best described as a first harmonic, and the transmission of that wave, and subsequent reflection of that arbitrary signal can not lack basic waveform properties. An ultrasound wave, which is

transmitted inherently, *HAS* a fundamental frequency, and the reflection of such a wave off of a variable cavity would contain noise and be a function of that transmitted waveform (harmonic). The data returned and analyzed by any ultrasound system is going to end up as a function of the frequency transmitted and the distance traveled/impedance encountered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-7 rejected under 35 U.S.C. 102(b) as being anticipated by Ganguly et al (US 6,213,949 B1). Ganguly et al disclose an apparatus capable of measuring the volume of urine in a bladder of an individual through a non-invasive ultrasound technique including a transducer assembly with a plurality of ultrasound transducers (Fig 4), means for activating the ultrasound transducers (Fig 1), means for determining body cavity height and depth (Col 6 Line 5- Col 8 Line 25), as well as filling degree based on known values stored from a patients history (Col 8 Line 35-50). The apparatus also has means for detecting using echo travel time and other beam information, determining which beams intercept the fluid-filled body (Col 4 Line 1 – Col 5 Line 60), display means for display of the calculated fluid volume (Col 8 Line 35-50), means for selecting the number of transducers to indicate bladder filling level (Fig 4, Col 8 Line 15 –50), the storage of patient information for the selection of factors for use in

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volume calculation via a memory (Col 8 Line 35-50), a system provided to adjust the frequency of calculation and display readout (Fig 6, Col 8 Line 35-50), a transducer assembly for locating the walls of the bladder in a single cross-sectional plane (Col 4 Line 35 – Col 5 Line 60), means for showing correct positioning of the transducer assembly (Col 6 Line 30-50), connection to a housing with input device, processor, display, and power supply unit (Fig 6), as well as an ultrasound coupling material covering the transducer for patient convenience (Col 8 Line 25-35). Ganguly et al also disclose mounting the transducer assembly at a predetermined spatial location and angle (Col 3 Line 15-30), acoustically coupling the transducers to the skin of the patient (Col 8 Line 25-35), using multiple harmonics or frequency measurements from the transducers to establish boundary lines (Col 4 Line 1 – Col 7 Line 65), and include the entirety of the bladder in the ultrasound measurement, using specific frequencies for the establishment of wall features and alternate frequencies for the measurement of the bladder volume, using specific A-lines for the acquisition of data at selected depths including the front/back walls, and the middle of the human bladder (Col 4 Line 1 – Col 7 Line 65), using both echo data from approximate front and back wall locations to fit and compute a relative location of the outline or edges of the bladder (Col 4 Line 35-45, Col 6 Line 5-50), and finally establishing a volume, comparing that volume to a predetermined threshold value (Col 8 Line 35-50), storing that value for later comparison (Col 8 Line 35-50), and the use of narrow beams within the piezoelectric elements to produce conventional ultrasound signals.

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2. Regarding the amendment to claim 6 and later those rejected under 103 which have been amended to include the mention of difference signals, Ganguly et al disclose the use of averaging of signals reflected and subsequent filtering and subtraction to form difference signals for locating the area of interest. Accordingly, as is the property of ultrasound "Acoustic Power" in water (or reflected in a watery environment) would be equal to the acoustic output power at that time. The acoustic power, which is transmitted, would be variable over the cycles of the wave, and thereby the subtractions of signals reflected at different times yields signals, which are associated with different "acoustic powers" as mW/cm<sup>2</sup> varies over the cycle of a waveform. Intensity and pressure data will be the point to point variable data in comparison to "acoustic power" which only varies based on the cycle of the wave within a truly watery environment. In the absence of water (ie a non-full bladder) the power signal will be different, and that enables the use of the subtraction methods of Ganguly et al for the formation of difference signal data (Col 4 Line 55- Col 7 Line 45).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly et al in view of Chalana et al (US 7,041,059 B2). Ganguly disclose all that is listed above, mainly an apparatus capable of measuring the volume of urine in a

bladder of an individual through a non-invasive ultrasound technique including a transducer assembly with a plurality of ultrasound transducers (Fig 4), means for activating the ultrasound transducers (Fig 1), means for determining body cavity height and depth (Col 6 Line 5- Col 8 Line 25), as well as filling degree based on known values stored from a patients history (Col 8 Line 35-50). The apparatus also has means for detecting using echo travel time and other beam information, determining which beams intercept the fluid-filled body (Col 4 Line 1 – Col 5 Line 60), display means for display of the calculated fluid volume (Col 8 Line 35-50), means for selecting the number of transducers to indicate bladder filling level (Fig 4, Col 8 Line 15 –50), the storage of patient information for the selection of factors for use in volume calculation via a memory (Col 8 Line 35-50), a system provided to adjust the frequency of calculation and display readout (Fig 6, Col 8 Line 35-50), a transducer assembly for locating the walls of the bladder in a single cross-sectional plane (Col 4 Line 35 – Col 5 Line 60), means for showing correct positioning of the transducer assembly (Col 6 Line 30-50), connection to a housing with input device, processor, display, and power supply unit (Fig 6), as well as an ultrasound coupling material covering the transducer for patient convenience (Col 8 Line 25-35). Ganguly et al also disclose mounting the transducer assembly at a predetermined spatial location and angle (Col 3 Line 15-30), acoustically coupling the transducers to the skin of the patient (Col 8 Line 25-35), using multiple harmonics or frequency measurements from the transducers to establish boundary lines (Col 4 Line 1 – Col 7 Line 65), and include the entirety of the bladder in the ultrasound measurement, using specific frequencies for the establishment of wall features and

alternate frequencies for the measurement of the bladder volume, using specific A-lines for the acquisition of data at selected depths including the front/back walls, and the middle of the human bladder (Col 4 Line 1 – Col 7 Line 65), using both echo data from approximate front and back wall locations to fit and compute a relative location of the outline or edges of the bladder (Col 4 Line 35-45, Col 6 Line 5-50), and finally establishing a volume, comparing that volume to a predetermined threshold value (Col 8 Line 35-50), storing that value for later comparison (Col 8 Line 35-50), and the use of narrow beams within the piezoelectric elements to produce conventional ultrasound signals.

4. Ganguly et al do not disclose providing battery power to the device, attention is then directed to the secondary reference by Chalana which describes a similar diagnostic device using a portable system powered by a battery, and suggests that such a system may be either battery powered or powered conventionally as a matter of choice (Col 4 Line 40 – Col 5 Line 15). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the battery powered elements of Chalana et al with the bladder volume calculation system of Ganguly to provide a portable element for approximation of the volume of the fluid in the bladder of a patient.

#### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is attached to the references cited sheet mailed out with this action.



6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML  
10/22/07

  
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